TSANZ CLINICAL DOCUMENT DEVELOPMENT PROCESS, PUBLICATIONS, AND ENDORSEMENT POLICY

Contents

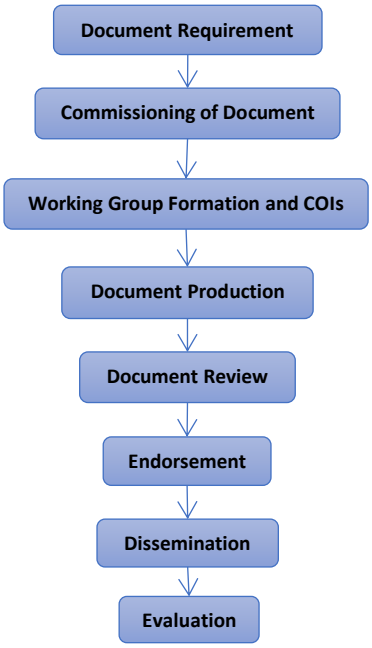
Abbreviations

CCRS – Clinical Care and Resources Sub-Committee
COI – Conflict of Interest
EOI – Expression of Interest
SIG – Special Interest Groups

TSANZ-Commissioned Documents

The process for clinical document development, from inception to fully disseminating the information and translating it into meaningful policy, should be controlled and transparent. At no time with the TSANZ accept sponsorship for guidelines or position papers from pharma, device or other companies with an actual or perceived conflict of interest. This overview contains a flow chart (Figure 1) of what is expected, coupled with a policy or template when appropriate.

Figure 1 *- Flowchart of the development process for TSANZ clinical documents*



Document requirement

The need for a clinical document will be identified by TSANZ members, Special Interest Groups (SIGs) or peer groups. The proposer of the clinical document should seek to immediately engage with the CCRS to scope available resources and support by completing the Proposal for a New Clinical Document online. This is a requirement for eventual TSANZ endorsement.

The CCRS will consider their decision to proceed with the development of documents in the form of:

- an update and revision of an existing clinical document, or;
- a new clinical document.

In general, TSANZ clinical documents should address issues applicable to all Australian States and Territories and New Zealand, unless there are important specific reasons to restrict them to certain states, territories or countries.

Commissioning of a clinical document

Proposals will be collated and considered by the Board based on greatest need, available evidence, and resources. Proposals will be accepted continuously and reviewed at each TSANZ Board meeting.

The TSANZ determines, with guidance from the CCRS, the requirement to produce a publication upon which;

- the publication type and aim will be registered with the TSANZ Clinical Administrator, and;

- a call for Expressions of Interest (EOI) will be advertised for a set period (usually 2 weeks). Conflicts of interest (COI), a 2-page CV and a full list of peer reviewed published articles will be obtained as part of the EOI process to assist in determining an appropriate working party and Chair(s).
- NB: only TSANZ members may submit an expression of interest. Non-TSANZ members may be invited to join the working party when EOIs are complete due to relevant expertise.

Working party formation

The CCRS will review expressions of interest and review their conflict of interest statements.

A working party is to be formed with the following considerations:

- identified working group leads (Chairs);
- appropriate number of people in the working party;
- the selection of authors should be widely discussed and transparent. Working groups should reflect the diversity of the Society and end users, considering geography, disciplines, gender, seniority and First Peoples;
- the stakeholder representation in the working party, including partner organisations and consumers (inclusion of consumers from the beginning of the process is strongly encouraged, to ensure that the document reflects their needs and priorities); and
- key timings agreed for progress and due date.

The CCRS will recommend the working group to the TSANZ Board for final approval.

Before the working party's first meeting, every member of the working party must:

- complete a COI (this usually occurs during the EOI process); and
- sign a Confidentiality Agreement.

The working party must have clearly defined, documented processed for reaching consensus.

Conflict of interest

All applicants wishing to join the working party must fill out and sign the TSANZ Conflict of Interest for Authors and Reviewers in reference to the clinical document prior to being accepted to join the working party. The Chair(s) of the working party will be responsible for ensuring all conflict of interest statements are kept up to date and all declared interests managed. A statement of conflict of interests must be included in all publications.

For further details regarding Conflict of Interest, see the TSANZ Conflict of Interest Policy.

Document production

Once a working party has been formed, document production may commence. Working parties must adhere to the Guidelines for Clinical Document Working Parties. Chairs must provide a progress report to the CCRS every six-months.

Where the group feels that they do not have the required skills amongst their membership (e.g. methodology or systematic review skills), the CCRS will assist the group to access these skills amongst the broader TSANZ membership. Occasionally, the TSANZ Board may approve funding for a specialist

librarian or medical writer to assist with the document development process, where the document is considered a priority for the Society. The Board will evaluate all requests for such assistance on a case by case basis.

If suitable resources are already available elsewhere (e.g. guidelines used in other countries), it may be more appropriate to adopt or modify these instead of generating new ones. Similarly, if relevant systematic reviews are already available, these should be used to underpin guideline development, rather than generating new ones.

The word limit for clinical documents will depend on the purpose of the document and plans for publication. It is a responsibility of the working group Chair/s to discuss this with the CCRS chair at the beginning of document production.

The final document must be approved by the CCRS, who will recommend it to the TSANZ Board for endorsement. The submission of documents to the CCRS involves a thorough procedural and content review, and will usually include editorial suggestions, and the document may require revision before it is finally accepted.

Types of clinical documents

There are two types of clinical documents: clinical practice guidelines; and position papers. The type of clinical document being developed will be determined before the EOI process begins.

Clinical practice guidelines

Clinical Practice Guidelines are documents that foster best clinical practice and promote consistency and equity of health care in Australia and New Zealand. These guidelines should be based on the systematic identification and synthesis of the best available scientific evidence.

Guidelines are the only TSANZ documents in which recommendations for clinical practice can be made. Recommendations can be made because the rigorous process underpinning a clinical practice guideline allows the Society to be confident that the recommendations are robust and underpinned by sufficient evidence to guide clinical practice.

TSANZ guidelines should aspire to meet the requirements of the peak national bodies in Australia and New Zealand, such as the National Health and Medical Research Committee (NHMRC updated 2016).

Guidelines developed should follow the 2016 NHMRC Standards for Guidelines. Working parties should familiarise themselves with the NHMRC resources for guideline developers.

Requirements for TSANZ Clinical Practice Guidelines

The requirements for TSANZ Clinical Practice Guidelines are:

- the purpose of the guideline is clearly stated, including the intended users and the population of interest;
- a systematic review of the literature is conducted by a CCRS approved methodologist, which includes:
    - a documented methodology for the review;
    - appropriate research/clinical questions in PICO format;
    - inclusion and exclusion criteria clearly stated;

  - a documented search strategy, including the search period;
  - systematic synthesis and grading of quality of the body of evidence for each clinical question; and
  - the link between evidence and guideline recommendations is clearly documented;
- the recommendations are graded in accordance with the GRADE system (or equivalent for international collaborative guidelines);
- consumer representatives are included on the guideline development group;
- the guideline development group includes representatives from a range of professions and disciplines that are relevant to the scope of the guideline;
- there is evidence of peer review external to the guideline development group;
- a dissemination plan for the guideline is clearly described;
- the expiry date for the guideline is stated;
- a list of members of the guideline development group is included; and
- a conflict of interest statement for each of the members of the guideline development group is included.

Position papers

Position papers present TSANZ positions on:

- clinical practice, especially in the areas of emerging diagnostic and therapeutic modalities where insufficient data exists to write a formal clinical guideline;
- public health policy, including health service delivery and government policy; and
- clinical and basic science research relevant to the area of respiratory medicine.

Recommendations for clinical practice cannot be made in a position paper, although suggested approaches to clinical care can be outlined.

The working party may choose to include a systematic review and formal assessment of the quality of evidence, however this is not mandatory. A clear statement on the evidence that has been used, how this has been sourced and evaluated, and how conclusions have been made should be included. If a systematic review is included, the working party must include an experienced methodologist, approved by the CCRS.

Requirements for TSANZ Position Papers

Requirements for TSANZ Position Papers are:

- the purpose of the position paper is clearly stated, including the intended users and the population of interest;
- the position paper development group includes representatives from a range of professions and disciplines that are relevant to the scope of the position paper;
- consumer representatives are included on the position paper development group;
- there is evidence of peer review external to the position paper development group;

- a dissemination plan for the position paper is clearly described;
- the expiry date for the position paper is stated;
- a list of members of the position paper development group is included; and
- a conflict of interest statement for each of the members of the position paper development group is included.

Evidence used in clinical documents

It is anticipated that TSANZ guidelines and position papers will be read and considered by a broad audience including the membership of the society, but also other professionals, other professional bodies, government and non-government agencies. From that perspective it is clearly preferable that a consistent approach to assessing the quality of evidence and the strength of recommendations is applied. At this stage a standard approach has not been adopted by the NHMRC. In the interim the TSANZ will recommend that for guidelines (and where applicable position papers) that a system of assessment of both the evidence and the strength of recommendations be used. The recommendation currently is to use the GRADE system, as it is internationally recognised, clearly defines the difference between evidence and recommendations and specifies a transparent system for moving from evidence to recommendation.[1],[2],[3],[4]

Peer review of clinical documents

The manuscript will be reviewed by nominees of the relevant SIGs pertaining to the publication with a focus on the document content. The CCRS will review the document with a focus on process. The CCRS reserves the right to request additional reviewers from inside or outside the Society. All content-matter expert reviewers must fill in the Conflict of Interest for Authors and Reviewers and the TSANZ Confidentiality Agreement.

Feedback will be issued to the working party for detailing any further requirements or recommendations required prior to endorsement.

For publications planning to publish with Respirology, the TSANZ and Respirology reviews may occur simultaneously.

Endorsement

Once the clinical document has been reviewed by the CCRS and relevant SIG(s), the CCRS will make a recommendation about whether the document should be endorsed in its current form. Each clinical document will be tabled for review by the TSANZ Board at their next Board Meeting. If there is a

[1] Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. Bmj. 2008 Apr 26;336(7650):924-6. PubMed PMID: 18436948. Pubmed Central PMCID: 2335261.

[2] Jaeschke R, Guyatt GH, Dellinger P, Schunemann H, Levy MM, Kunz R, et al. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive. Bmj. 2008;337:a744. PubMed PMID: 18669566.

[3] Schunemann HJ, Oxman AD, Brozek J, Glasziou P, Bossuyt P, Chang S, et al. GRADE: assessing the quality of evidence for diagnostic recommendations. ACP journal club. 2008 Dec 16;149(6):2. PubMed PMID: 19071869.

[4] Schunemann HJ, Oxman AD, Brozek J, Glasziou P, Bossuyt P, Chang S, et al. GRADE: assessing the quality of evidence for diagnostic recommendations. Evidence-based medicine. 2008 Dec;13(6):162-3. PubMed PMID: 19043023.

specific urgency for publication, this process may be fast-tracked and an out-of-session endorsement may be requested. The timeline for this is usually 2 weeks.

Endorsement will include:

- registration of Board endorsement by TSANZ Office; and
- badging (or co-badging if it is a joint paper) of the publication with the TSANZ logo.

Publication

During the proposal stage, the TSANZ Board, with recommendations provided by the CCRS, will decide whether the clinical document is to be submitted to a journal. Respirology will be the first consideration for all publications, unless another agreement has been reached between the CCRS and the working party.

When a clinical document is publishing in a journal it may be made available as Open Access, subject to Board approval, with the TSANZ (in partnership with any joint-organisation) accepting the cost for this dependent upon reasonable negotiation with the working party and publisher. If the TSANZ Board determines a clinical document is to be published as Open Access in Respirology and funded by the Society, then publications will be licensed as CC-BY-NC.

The TSANZ may assert copyright ownership over guidelines we commission.

Dissemination and further education requirements

A dissemination plan must be developed alongside each document. This plan will be developed by the TSANZ staff in consultation with the working party.

- In order to enhance access to TSANZ guidelines and position papers, all clinical documents will be made available via the TSANZ website, either in full or as a link to the publication. Where a clinical document is published in a journal, it will not be published on the TSANZ website until the publication embargo has lifted.
- All working parties will be invited to host a TSANZ webinar to present their clinical document. This will be organised with the Continuing Education Officer.
- If applicable, a training course based on the clinical practice guidelines will be developed with the Education and Training Sub-committee.
- For clinical practice guidelines, the working party will be required to create an Audit Standards of Care Template as a companion to the guidelines. This template is to be made available to all TSANZ members. The template must be in the form of a checklist which provide questions for what is required to be compliant. E.g. For oxygen audits, there would be a yes/no question for whether a prescription has been written for patients requiring high flow nasal oxygen.

Evaluating impact

Each TSANZ document should have a plan to evaluate its impact, which is documented alongside the dissemination plan. The evaluation should consider process, clinical outcomes and policy. For instance, consider;

- number of downloads from TSANZ website;
- number of downloads from journal website;

- number of derivatives developed, e.g. training packages or quality standards;
- number of people undertaking training, where relevant;
- media mentions;
- evidence of impact on health care policy and clinical practice; and
- evidence of impact on patient outcomes.

Update

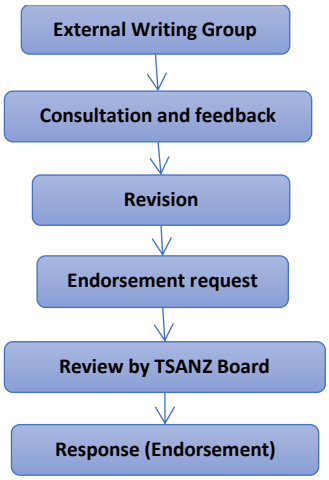
All TSANZ documents will be endorsed for a period of five years, unless agreed otherwise during the review process. Prior to five years, the CCRS will ask the relevant SIG and/or the original working party to review the document for currency and the need for updating.

Documents from Other Organisations

TSANZ members who are involved in the development of documents for external bodies are encouraged to liaise with the CCRS to determine whether TSANZ endorsement might be relevant.

The process for endorsement of external clinical documents should allow for review and improvement of resources and covers both the guideline development process and content. This overview contains a flow chart (Figure 2) of what is expected.

Figure 2 - Flowchart of the development process for clinical documents from external organisations



Consultation request

The TSANZ will receive requests to review and consult on publications which have been produced external to the Society. All requests should be sent to the TSANZ Clinical Administrator to ensure tracking of requests and coordination of the review. The external organisation will be requested to complete the consultation checklist prior to the consultation. The consultation may or may not be accompanied by a request for endorsement.

The manuscript will be reviewed by a number TSANZ of reviewers including, but not exclusive to, two representatives of the relevant SIG/s. The CCRS will review the consultation checklist from a procedural view. Feedback will be issued to the external working party detailing any further requirements or recommendations required prior to endorsement.

All content-matter expert reviewers should fill in the Conflict of Interest for Authors and Reviewers.

Requests for TSANZ review should normally be regarded as a request to comment on and improve the document. Requests should therefore allow sufficient time for the sub-committee to do this. Requests not submitted with sufficient time to permit full evaluation, will usually not be considered.

Endorsement request

The CCRS Chair will determine the stance of the Society and if the external document will be considered with consideration to the information provided in the consultation checklist. The external document will enter review step once the following has occurred;

- The cost of consultation is agreed,
- The timeline of consultation is agreed,
- The document is registered by the Clinical Administrator, and
- The author list and completed COIs are noted by the TSANZ Office.

Review by TSANZ Board

The TSANZ Board will review the clinical document from a strategic point of view. Endorsement of the clinical document will be determined by the TSANZ Board, with a recommendation provided by the CCRS.

Dissemination via TSANZ

One the external document is published, it will be disseminated via the TSANZ eNews or Weekly update.